4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3275]

Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to an IND, NDA, BLA, or ANDA." The draft guidance provides recommendations to industry and FDA staff regarding the content and submission procedures for use-related risk analyses, human factors validation study protocols and reports, threshold analyses, and comparative use human factors study protocols and reports.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comments in this review.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-3275 for "Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to an IND, NDA, BLA or ANDA." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Quynh Nhu Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4408, Silver Spring, MD 20993, 301-796-6273, email: quynht.nguyen@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Contents of Threshold Analyses and Human Factors Submissions to an IND, NDA, BLA, or ANDA." This document provides guidance to industry on the content and submission procedures for human factors (HF) submissions to promote efficient Agency review.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that drug products submitted for approval under section 505(b) be proven safe and demonstrate substantial evidence of effectiveness for the product's intended use (21 U.S.C. 355(b)). Under section 351 of the Public Health Service Act (42 U.S. 262), FDA licenses a biological product based on a demonstration that it is safe, pure, and potent, and that it is manufactured in a facility designed to ensure the product continues to be safe, pure, and potent. As part of evaluating drug and biologic products for safety and effectiveness, FDA will evaluate HF data submitted by sponsors in support of the product user interface when submission of such data is warranted. For products that sponsors intend to submit as an abbreviated new drug application (ANDA), the sponsor can rely on the Agency's previous finding that the listed drug is safe and effective so long as the sponsor can demonstrate certain findings. Certain products, including drug-device combination products, may warrant threshold analyses and additional data, such as data from comparative HF studies.

This draft guidance provides recommendations to industry and FDA staff regarding the content and submission procedures for use-related risk analyses, human factors validation study protocols and reports, threshold analyses, and comparative use HF study protocols and reports. This draft guidance applies to submissions for the following types of products:

- Human prescription drug products, including biologics, that are the subject of an investigational new drug application (IND), a new drug application (NDA), a biologics license application (BLA), or an abbreviated new drug application (ANDA), and supplements to these applications
- Human nonprescription drug products that are the subject of an IND, NDA, or ANDA

This draft guidance does not describe when threshold analyses or HF submissions are warranted for any particular application pathway, the processes or procedures associated with their review, or the methods used by the Agency for evaluation. Furthermore, this draft guidance does not describe the methods used to design, conduct, or analyze HF studies.

This draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on "Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to an IND, NDA, BLA or ANDA." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 and Form FDA 1571 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,

https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or https://www.regulations.gov.

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-21243 Filed: 9/28/2018 8:45 am; Publication Date: 10/1/2018]